General

Guideline Title

Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems).

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Aug. 60 p. (Diagnostics guidance; no. 13).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Cardiac Surgery

The ROTEM system and the TEG system are recommended to help detect, manage and monitor haemostasis during and after cardiac surgery.

The Sonoclot system is only recommended for use in research to help detect, manage and monitor haemostasis during and after cardiac surgery. Research is recommended into the clinical benefits and cost effectiveness of using the Sonoclot system during and after cardiac surgery.

Healthcare professionals using the ROTEM system and the TEG system during cardiac surgery should have appropriate training and experience with these devices.

Emergency Control of Bleeding

There is currently insufficient evidence to recommend the routine adoption of viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems) in the National Health Service (NHS) to help detect, manage and monitor haemostasis in the emergency control of bleeding after trauma and during postpartum haemorrhage. Research is recommended into the clinical benefits and cost effectiveness of using viscoelastometric point-of-care testing to help in the emergency control of bleeding after trauma or during postpartum haemorrhage.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Bleeding during and after cardiac surgery
- Bleeding after trauma and during postpartum haemorrhage

Guideline Category

Diagnosis

Management

Technology Assessment

Clinical Specialty

Cardiology

Emergency Medicine

Hematology

Internal Medicine

Obstetrics and Gynecology

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Emergency Medical Technicians/Paramedics

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate the clinical and cost-effectiveness of viscoelastometric testing (using the ROTEM, TEG or Sonoclot systems) to detect, manage and monitor haemostasis in cardiac surgery and in the emergency control of bleeding after trauma and during postpartum haemorrhage

Target Population

- Adult patients (18 years and older) having cardiac surgery
- Adult patients (18 years and older) who need emergency control of bleeding after trauma and during postpartum haemorrhage.

Interventions and Practices Considered

Viscoelastometric point-of-care testing devices (ROTEM, TEG and Sonoclot systems)

Major Outcomes Considered

- Number of patients receiving blood product transfusion
- Bleeding
- Re-operation
- Surgical cause of bleeding
- Length of intensive care unit stay
- Length of hospital stay
- Transfusion-related complications
- Mortality
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare a Diagnostics Assessment Report (DAR). The DAR for this diagnostic guidance was prepared by the Kleijnen Systematic Reviews Ltd in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Systematic Review Methods

Search Strategy

Search strategies were based on index test (ROTEM Delta, TEG and Sonoclot), as recommended in the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care and the Cochrane Handbook for Diagnostic Test Accuracy Reviews.

Candidate search terms were identified from target references, browsing database thesauri (e.g., Medline MeSH and EMBASE EMTREE), existing reviews identified during the rapid appraisal process and initial scoping searches. These scoping searches were used to generate test sets of target references, which informed text mining analysis of high-frequency subject indexing terms using Endnote reference management software. Strategy development involved an iterative approach testing candidate text and indexing terms across a sample of bibliographic databases and aimed to reach a satisfactory balance of sensitivity and specificity.

Search strategies were developed specifically for each database and the keywords associated with ROTEM, thromboelastography, thromboelastometry and Sonoclot were adapted according to the configuration of each database.

Primary Clinical Effectiveness Searches

Primary searches were undertaken for randomised controlled trials in thromboelastography, thromboelastometry, and Sonoclot, and these searches were limited with an objectively-derived study design filter, where appropriate.

See Section 3.1.1.1 in the DAR for the list of databases that were searched for relevant studies from inception to December 2013.

Viscoelastic (VE) Testing in Postpartum Haemorrhage and Trauma

A second series of focused searches were undertaken without a study design filter to identify relevant references reporting thromboelastography, thromboelastometry and Sonoclot in post-partum haemorrhage or trauma response.

The following databases were searched for relevant studies from inception to December 2013:

- MEDLINE (OvidSP): 1946-2013/09/wk 3
- MEDLINE In-Process Citations and Daily Update (OvidSP): up to 26.9.13
- EMBASE (OvidSP): 1974-2013/11/05

No restrictions on language or publication status were applied. All search strategies are presented in Appendix 1 in the DAR. The main EMBASE strategy for each search was independently peer reviewed by a second Information Specialist, using the Canadian Agency for Drugs and Technologies (CADTH) Peer Review checklist. Identified references were downloaded in Endnote X4 software for further assessment and handling. References in retrieved articles and the websites set up by the manufacturers of ROTEM Delta and Sonoclot were also screened for additional references. The manufacturers of ROTEM and Sonoclot and clinical experts submitted references of relevant publications for consideration for inclusion in the review. The final list of included papers was checked on PubMed for retractions, errata and related citations.

Inclusion and Exclusion Criteria

See Table 6 in the DAR (see the "Availability of Companion Documents" field) for inclusion criteria.

Inclusion Screening

Two reviewers independently screened the titles and abstracts of all reports identified by searches and any discrepancies were discussed and resolved by consensus. Full copies of all studies deemed potentially relevant were obtained and the same two reviewers independently assessed these for inclusion; any disagreements were resolved by consensus. Details of studies excluded at the full paper screening stage are presented in Appendix 4 in the DAR.

Studies cited in materials provided by the manufacturers of ROTEM, TEG or Sonoclot were first checked against the project reference database, in Endnote X4; any studies not already identified by the searches were screened for inclusion following the process described above.

Assessment of Cost-effectiveness

Review of Economic Analyses of VE Testing

Search Methods

Searches were undertaken to identify cost-effectiveness studies of viscoelastic (VE) point-of-care testing. As with the clinical effectiveness searching, the main EMABSE strategy for each set of searches was independently peer reviewed by a second Information Specialist, using the CADTH Peer Review checklist. Search strategies were developed specifically for each database and searches took into account generic and other product names for the intervention. All search strategies are reported in Appendix 1 in the DAR.

The following databases were searched for relevant studies from inception to November 2013:

- MEDLINE (OvidSP): 1946-2013/10/wk 4
- MEDLINE In-Process Citations and Daily Update (OvidSP): up to 2013/11/05
- EMBASE (OvidSP): 1974-2013/11/05
- National Health Service Economic Evaluation Database (NHS EED) (Wiley): Issue 4. October/2013
- EconLIT (EBSCO): 1990-2013/09/01
- Health Economic Evaluation Database (HEED) (Wiley): up to 2013/11/07 http://onlinelibrary.wiley.com/book/10.1002/9780470510933
- IDEAS via Research Papers in Economics (REPEC) (Internet): up to 2013/11/07 http://repec.org/

Identified references were downloaded in Endnote X4 software for further assessment and handling. References in retrieved articles were checked for additional studies.

Inclusion Criteria

Cost minimisation and cost-effectiveness studies that evaluated the use of TEG, ROTEM or Sonoclot compared to a control group (either concurrent or historical) consisting of no-testing, clinical judgement or standard laboratory tests (SLTs) were eligible for inclusion. Studies in children were excluded.

Number of Source Documents

Assessment of Clinical Effectiveness

The literature searches of bibliographic databases identified 8,960 references. After initial screening of titles and abstracts, 78 were considered to be potentially relevant and ordered for full paper screening. No additional papers were ordered based on screening of papers provided by test manufacturers, conference abstract hand searching or screening references of included studies; all studies cited in documents supplied by the test manufacturers, identified through reference screening or conference abstract screening had already been identified by bibliographic database searches. Figure 4 in the Diagnostics Assessment Report (DAR) shows the flow of studies through the review process, and Appendix 4 in the DAR provides details, with reasons for exclusions, of all publications excluded at the full paper screening stage.

Based on the searches and inclusion screening, 39 publications of 33 studies were included in the review. The Assessment Group included 11 randomised controlled trials (RCTs) (14 publications) evaluating ROTEM and TEG in cardiac surgery patients; as no RCTs evaluating Sonoclot were identified, they also included three prediction studies that evaluated Sonoclot. They included one ongoing RCT, one controlled clinical trial (CCT) and 15 prediction studies (18 publications) in trauma patients and two prediction studies in women with postpartum haemorrhage (PPH).

Assessment of Cost-effectiveness

- The searches identified 331 records of which five studies fulfilled the inclusion criteria, two were only available as conference abstracts (see Figure 25 in the DAR). Three were conducted in cardiac patients, one in patients undergoing liver transplant, and one in both cardiac and liver transplant patients. One study was a formal cost-effectiveness analysis of viscoelastometric (VE) devices in cardiac and liver transplant patients. The other four studies were cost-minimisation studies performed alongside a retrospective before/after study.
- A de novo model was also presented.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare a Diagnostics Assessment Report (DAR). The DAR for this diagnostic guidance was prepared by the Kleijnen Systematic Reviews Ltd in collaboration with Erasmus University Rotterdam and Maastricht University (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Systematic Review Methods

Data Extraction

Data were extracted on the following: participant characteristics; study design; inclusion and exclusion criteria; details of viscoelastic (VE) test and/or test parameters evaluated; details of standard laboratory tests (SLTs), where applicable; details of outcomes assessed (main outcomes were bleeding outcomes, transfusion outcomes, hospital/intensive care unit [ICU] stay, re-operation and mortality); results. Data were extracted by one reviewer, using a piloted, standard data extraction form and checked by a second; any disagreements were resolved by consensus. Full data extraction tables are provided in Appendix 2 in the DAR.

Quality Assessment

The methodological quality of included randomised controlled trials (RCTs) was assessed using the Cochrane Risk of Bias Tool. Prediction studies were assessed for methodological quality using QUADAS-2. Risk of bias assessments were undertaken by one reviewer and checked by a second reviewer, and any disagreements were resolved by consensus.

The results of the risk of bias assessments are summarised and presented in tables and graphs in the results of the systematic review and are presented in full, by study, in Appendix 3 in the DAR.

Methods of Analysis/Synthesis

The Assessment Group members provided a narrative synthesis involving the use of text and tables to summarise data to show differences in study designs, population, VE device and potential sources of bias for each of the studies being reviewed. Studies were organised by research question addressed (study population), outcome and VE device.

RCTs Comparing VE Testing with No Testing

Meta-analysis was used to estimate summary effect sizes for outcomes evaluated in multiple studies for which sufficient data were reported. Data were only reported in an appropriate format to permit pooling for dichotomous data. Summary relative risks (RR) together with 95% confidence intervals (CIs) were estimated using DerSimonian and Laird random effects models. Heterogeneity was investigated visually using forest plots and statistically using the I^2 and Q statistics. Data were pooled for all VE devices combined and stratified according to VE device; if no difference based on VE device was found a summary estimate was calculated comparing VE testing irrespective of VE device to no testing. Where multiple sets of data were reported for the same outcome for a single study, for example pre-operative, post-operative and total number of patients transfused, a single dataset was selected. The dataset relating to the largest number of participants or latest time point was selected.

For continuous outcomes, data were not reported in sufficiently similar format to permit pooling. Only a small number of studies reported data as means and standard deviations or CIs, which would have allowed calculations of mean differences, and there were insufficient studies reporting data in this format to pool data. Most studies reported data as medians (some with interquartile ranges [IQRs]) and some reported p-values for comparisons of the differences between medians, usually estimated using the Mann Whitney or Wilcoxon rank sum tests. Some studies only reported medians with no measure of distribution around the median or estimation of the significance of the difference between groups. The Assessment Group members summarised the results for continuous outcomes in a table showing the measure of effect reported in the study (mean or median with associated standard deviation, CI, IQR or range), the effect estimate in the VE testing and in the control group and any reported p-value for the comparison between the two groups.

See Section 3 in the DAR for additional information on clinical effectiveness analysis.

Assessment of Cost-effectiveness

Quality Assessment

Full cost-effectiveness studies were appraised using the Drummond checklist.

Model Structure and Methodology

Cardiac Surgery

The Assessment Group members adopted the model structure used by the Health Technology Assessment (HTA) undertaken for National Health Service (NHS) Scotland in 2008, which was largely based on a cost-effectiveness study of cell salvage and alternative methods of minimising perioperative allogeneic blood transfusion. As these studies were undertaken in 2008 and 2006, respectively, more recent data sources were used to update the input parameters of the model wherever possible.

The model is based on a decision tree that starts with the choice of strategy to be followed, i.e., VE device (ROTEM, TEG, or Sonoclot) or SLTs.

Within each strategy, patients then either do or do not receive a transfusion.

Red blood cell (RBC) transfusion, where it occurs, may be associated with adverse events or complications. Most complications are a consequence of RBC transfusion, although some were modelled as a consequence of any transfusion.

The model's time horizons were set to one month and one year because the benefits of a reduction in RBC transfusion were considered to have occurred within this timeframe. At one month, the model reflects the period of hospitalisation and accordingly captures the impact of complications related to surgery and blood loss, transfusion-related complications and infection caused by bacterial contamination (see Figure 26 in the DAR for cost-effectiveness model structure).

Patients with Coagulopathy Induced by Trauma

The model for trauma patients has largely the same structure as the model in cardiac surgery patients. The only difference relates to the "surgery and/or transfusion related complications", which were replaced with "trauma and/or transfusion related complications" - acute respiratory distress syndrome (ARDS) and multiple organ failure (MOF).

Model Input Parameters

Whenever possible, parameters were estimated from the systematic review (Section 3 in the DAR). Where standard errors were not reported, estimates for the probabilistic sensitivity analysis (PSA) assumed a 95% CI with limits deviating 20% from the mean, as it was assumed that this would represent a reasonable range of variation.

See Section 4 in the DAR for more information on the methods used for cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Base-Case Results (Cardiac and Trauma Models)

For the cardiac model, all the viscoelastometric devices dominated (that is, were more effective and less costly than) standard laboratory tests. The External Assessment Group assumed the same treatment effects for each viscoelastometric testing device (quality-adjusted life years [QALY]=0.8773). The cost of Sonoclot was lower than that of ROTEM and TEG, and the device was associated with greater cost savings (£132) than either TEG (£79) or ROTEM (£43).

For the trauma model, all the viscoelastometric technologies dominated standard laboratory tests. The effectiveness of the devices was the same (QALY=0.5713). The cost of Sonoclot was lower than that of ROTEM or TEG and so this device was associated with greater cost savings (£818) than TEG (£721) or ROTEM (£688).

The results of other outputs from both the cardiac and trauma models showed that, compared with standard laboratory tests, the use of viscoelastometric devices is associated with lower mortality, a reduced probability of experiencing complications, and lower transfusion and hospitalisation costs. The probability of experiencing transfusion-transmitted infections was very low (almost zero) in both groups but lower in the viscoelastometric group.

Probabilistic Analysis Results (Cardiac and Trauma Models)

The impact of statistical uncertainties regarding the models input parameters was explored through probabilistic sensitivity analysis.

For the cardiac model, the scatter plot of the probabilistic sensitivity analysis outcomes in the cost-effectiveness plane was not very informative because the model only assumed a difference in costs between the technologies. The probabilistic sensitivity analysis confirmed that using standard laboratory tests is the strategy with the lowest probability of being cost effective. If the maximum acceptable incremental cost-effectiveness ratio (ICER) was £30,000 per QALY gained, the probability of cost effectiveness for each of the 3 viscoelastometric technologies compared with standard laboratory tests was 0.79 for ROTEM, 0.82 for TEG and 0.87 for Sonoclot. When the maximum acceptable ICER was higher than £30,000 per QALY gained, the cost-effectiveness probabilities converged to around 0.80 for all technologies.

Probabilistic sensitivity analysis results for the trauma model were similar to the cardiac model. The analysis confirmed that using standard laboratory tests was the strategy with the lowest probability of being cost effective. A comparison of ROTEM with standard laboratory tests found a cost-effectiveness probability equal to 0.96 for ROTEM for a ceiling ratio equal to £0. As the ceiling ratio increased, the cost-effectiveness acceptability curve for ROTEM converged to 0.87. A similar pattern was observed for TEG and Sonoclot.

Scenario Analysis Results

For the cardiac model, all scenario analyses suggested that ROTEM remained cost saving. The only exception was the number of tests run on each device per year. If the number of tests run on each device were reduced to 200, ROTEM no longer dominated standard laboratory tests, and ICER was £16,487 per QALY gained. The External Assessment Group estimated, using iterative analysis, that if all other parameters in the model remained unchanged, the costs of ROTEM and standard laboratory tests would be equal if 326 tests were run on ROTEM each year. At this level the ICER would be £0 per QALY gained. If the number of tests per year were reduced to 152, the ICER would be around £30,000 per QALY gained.

Additional scenario analyses for cardiac surgery suggested that when viscoelastometric testing is carried out in conjunction with standard laboratory testing, TEG was more effective and less costly (−£1) than standard laboratory testing alone and that the ICER for ROTEM and standard laboratory testing alone was £7487 per QALY gained. When the number of tests and type of assays used were varied, viscoelastometric testing dominated standard laboratory testing alone.

For the trauma model, all scenario analyses suggested that ROTEM remained cost saving. The iterative analysis performed to estimate the number of tests per year such that ROTEM would still be cost saving suggested a break-even value of 81 tests per year; at this level the ICER was £0 per QALY gained. When the number of tests per year was reduced to 65, the ICER was approximately £30,000 per QALY gained.

Additional scenario analyses for trauma surgery suggested that when viscoelastometric testing is carried out in conjunction with standard laboratory testing, ROTEM and TEG dominated (−£558 and −£591 respectively) standard laboratory testing alone. When the number of tests and type of assays used were varied, viscoelastometric testing dominated standard laboratory testing alone.

For the trauma model, threshold analysis on the combined effect of a reduction in the percentage of patients transfused and the blood volumes transfused (assuming that equal volumes of blood were transfused in the viscoelastometric testing and standard laboratory test groups) showed that, at saving (with an ICER of £0 per QALY gained). When the relative risk of transfusion increased to 0.9874, the ICER of ROTEM compared with standard laboratory tests was £30,000 per QALY gained.

Reducing baseline transfusion risk in the standard laboratory test group (assuming that equal volumes of blood were transfused in the viscoelastometric testing and standard laboratory test groups) showed that ROTEM was no longer cost saving at a transfusion rate of 5%, and that the ICER was £30,000 per QALY gained for a transfusion rate of 4%. This compares with a transfusion rate of 32% used in the base-case analysis. When the analysis was repeated with an increased relative risk of red blood cell transfusion (from 0.88 to 0.95), the ICER was above £30,000 per QALY gained for a transfusion rate of 8% or less. After reducing the probability of complications related to trauma and/or transfusion, transfusion-related complications and transfusion-related infection to zero, ROTEM remained cost saving with a reduction in costs of £372.

Considerations

The Committee discussed the results of the base-case analysis on the use of viscoelastometric testing in cardiac surgery. It noted that viscoelastometric testing dominated standard laboratory tests (that is, was more effective and less costly) producing more QALYs; 0.0047 and costing less (-£43 for ROTEM and -£79 for TEG). The Committee also noted that results of other outputs from the model show that the use of viscoelastometric devices is associated with lower mortality, a reduced probability of experiencing complications, and less transfusion and hospitalisation. Based on the level of clinical evidence, the Committee did not consider that the Sonoclot system was of equivalent clinical effectiveness to the ROTEM and TEG systems. The Committee did not therefore consider the results of the cost-effectiveness analysis for the Sonoclot system to be robust. The Committee concluded that the use of the ROTEM and TEG systems to help detect, manage and monitor haemostasis in cardiac surgery is cost effective when compared with standard laboratory tests alone.

See Sections 5 and 6 in the original guideline document for additional discussion of the economic analysis.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostic Advisory Committee considered a systematic review and cost-effectiveness analysis prepared by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems) for detecting, managing and monitoring haemostasis

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- The National Institute for Health and Care Excellence (NICE) has developed tools (see also the "Availability of Companion Documents" field), in association with relevant stakeholders, to help organisations put this guidance into practice. This may include adoption support work from the NICE Health Technologies Adoption Programme.
- NICE will support this guidance with a range of activities to promote the recommendations for further research. This will include incorporating the research recommendations in section 7 of the original guideline document into the NICE guidance research recommendations database and highlighting these recommendations to public research bodies. The research proposed will also be put forward to NICE's Medical Technologies Evaluation Programme research facilitation team for consideration of the development of specific research protocols.

Implementation Tools

Chart Documentation/Checklists/Forms

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Detecting, managing and monitoring haemostasis: viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Aug. 60 p. (Diagnostics guidance; no. 13).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Aug

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Professor Adrian Newland (*Chair*), Diagnostics Advisory Committee; Dr Mark Kroese (*Vice Chair*), Diagnostics Advisory Committee and Consultant in Public Health Medicine, PHG Foundation, Cambridge and UK Genetic Testing Network; Professor Ron Akehurst, Professor in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield; Professor Paul Collinson, Consultant Chemical Pathologist and Professor of Cardiovascular Biomarkers, St George's Hospital; Dr Sue Crawford, General Practitioner (GP) Principal, Chillington Health Centre; Professor Ian A Cree, Senior Clinical Advisor, NIHR Evaluation Trials and Studies Coordinating Centre, University of Southampton; Professor Erika Denton, National Clinical Director for Diagnostics, NHS England, Honorary Professor of Radiology, University of East Anglia and Norfolk and Norwich University Hospital; Dr Steve Edwards, Head of Health Technology Assessment, BMJ Evidence Centre; Mr David Evans, Lay Member, Safety Engineer and Occupational Hygienist; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula Technology Assessment Group (PenTAG); Professor Noor Kalsheker, Professor of Clinical Chemistry, University of Nottingham; Mr Matthew Lowry, Director of Finance and Infrastructure, Doncaster and Bassetlaw Hospitals NHS Foundation Trust; Dr Michael Messenger, Deputy Director and Scientific Manager NIHR Diagnostic Evidence Co-operative, Leeds; Dr Peter Naylor, General Practitioner (GP), Chair Wirral Health Commissioning Consortia; Dr Dermot Neely, Consultant in Clinical Biochemistry and Metabolic Medicine, Newcastle upon Tyne Hospitals NHS Foundation Trust; Dr Richard Nicholas, Consultant Neurologist, Honorary Senior Lecturer, Heatherwood and Wexham Park Hospitals; Dr Gail Norbury, Consultant Clinical Scientist, Guys Hospital; Dr Diego Ossa, Director of Market Access Europe, Novartis Molecular Diagnostics; Professor Mark Sculpher, Professor of Health Economics at the Centre for Health Economics, University of York; Dr Steve Thomas, Consultant Vascular and Cardiac Radiologist at Sheffield Teaching Hospitals Foundation Trust; Mr Paul Weinberger, CEO, DiaSolve Ltd, London; Mr Christopher Wiltsher, Lay Member

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site. Also available for download as a Kindle or EPUB ebook from the NICE Web site.

Availability of Companion Documents

The following are available:

- Whiting P, Al M, Westwood ME, Corro Rammos I, Ryder S, Armstrong N, Misso K, Ross J, Severens JL, Kleijnen J. Viscoelastic point-of-care testing to assist with the diagnosis, management and monitoring of haemostasis: a systematic review and cost-effectiveness analysis. Diagnostics assessment report. York (UK): Kleijnen Systematic Reviews Ltd; 2014. 334 p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site.
- NICE diagnostic support for viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems). London (UK): National Institute for Health and Care Excellence; 2014 Aug. Electronic copies: Available from the NICE Web site.
- Adult intensive care unit management of post-operative bleeding. Example bleeding algorithm. The Royal Brompton and Harefield NHS Foundation Trust. 1 p. Electronic copies: Available from the NICE Web site.

- Competency checklist. Use of Haemoscope TEG® 5000 Haemostasis Analyser. Example competency checklist. London (UK): National Institute for Health and Care Excellence. 2 p. Electronic copies: Available from the NICE Web site .
- Standard operating procedure. Use of Haemoscope TEG® 5000 Haemostasis Analyser. Example standard operating procedure. London (UK): National Institute for Health and Care Excellence. 11 p. Electronic copies: Available from the NICE Web site .
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Detecting, managing and monitoring haemostasis - viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems): information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Aug. (Diagnostics guidance; no. 13). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

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